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REMARKS

Claims 1, 4, 5, and 7 to 10 have been examined. Claims 1, 2, 4, 6, 10, and 11 to 24 have been canceled. Claim 3 has been alleged to be drawn to a non-elected species. However, because the claim does encompass the elected species, ^{13}C-cyclodextrin, Applicants respectfully request that claim 3 be included in the elected group.

Furthermore, new method claims 43 to 63 which encompass the elected species have been added. The new claims are fully supported by the examples in the present specification. For example, claims 43 to 51 are supported by original claims 16 to 24 and by the description page 6, line 34 to page 8, line 3. Claims 52 and 58 and their dependent claims are supported, for example, by the description on page 13, lines 3 to 13. No new matter has been added.

Thus, claims 3, 5, 7 to 9, and 43 to 63 are pending.

Claim Rejection Under 35 USC §112

Claim 5 has been amended to clarify what the C-modifying groups are. Support for the amendments are found, for example, on page 13, lines 3 to 13. Withdrawal of the indefinite rejection is requested.

The rejection against claim 10 is rendered moot as it was canceled.

Claim Rejection Under 35 USC §103

Claims 1, 4, 5, and 7 to 10 have been rejected as being unpatentable over Jindrich et al. ("Jindrich") in view of DeRosch et al. ("DeRosch"). Applicants submit that claims 1, 4, 5, and 7 to 9 as well as claim 3 are not obvious over the cited prior art references for the following reasons.

Jindrich does describe creating mono-2-O-alkylcyclomaltoheptaoses (see table 1 and page 78). However, in terms of labeled cyclodextrin, the prior art only gives an example of

creating ^{13}C-methyl-cyclodextrin by methylating cyclodextrin with ^{13}C-enriched dimethyl sulfate (see page 79, last complete paragraph). It does not teach any other labeled cyclodextrins or suggest making other ^{13}C labeled-compounds.

DeRosch describes adding the cyclodextrin to the radiopharmaceutical kits to stabilize the radio-components, e.g. radioisotope binding ligands (column 4, line 22), of the radiopharmaceutical kits (see, for example, column 1, lines 5 to 12; and column 2, lines 63 to column 3, line 5). The cyclodextrin itself is not labeled. The reference says nothing about creating a ^{13}C-cyclodeterin or, for that matter any, ^{13}C-labeled oligosaccharides or polysaccharides, or salts thereof.

The combination of Jindrich and DeRosch, therefore, would not have taught or suggested one skilled in the art to create labeled compounds other than ^{13}C-methyl-cyclodextrin.

Therefore, the references do not teach or suggest the present invention as claimed in claim 5, which recites:

> 5. (Twice Amended) A ^{13}C-labeled oligosaccharide or polysaccharide, or a salt thereof comprising:
>
> ^{13}C-cyclodextrin or at least one sugar molecule constituting the oligosaccharide or polysaccharide being modified with at least one modifying group,
>
> wherein said sugar molecule or modifying group is ^{13}C-labeled, and said modifying group is selected from a group consisting of a galactosyl group, a digalactosyl group, an alkoxyl group, a carbamoyl group, a pyrimidino group, an ethylidene group, and a benzylidene group.

^{13}C-methyl-cyclodextrin is not included in this claim as ^{13}C-methyl- is not part of the claimed modifying group. Thus, a person of ordinary skill in the art would not have found obvious the invention of claim 5 and all of its dependent claims. Applicants respectfully request that claim 5 and its dependent claims 3 and 7 to 9 be allowed over the cited prior art references.

New Claims

New method claims 42 to 51 are not disclosed, taught, or suggested by the cited prior art references. New claims 52 to 63 are directed to a method of measuring pancreatic exocrine

function by administering a compound of claim 5 to a subject. The invention of those claims are not disclosed, taught or suggested by the cited prior art references.

Attached is a marked-up version of the changes being made by the current amendment.

Applicant asks that all pending claims be allowed. Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

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Version with markings to show changes made

In the claims:

Claims 1, 2, 4, 6, 10, and 11 to 24 have been cancelled without prejudice.

Claims 3, 5, 7, and 9 have been amended as follows:

3. (Amended) The ^{13}C-labeled oligosaccharide or polysaccharide or a salt thereof according to claim [2] 5, which is not [hydrolyzed] hydrolyzable with α-glucosidase.

5. (Twice Amended) [The] A ^{13}C-labeled oligosaccharide or polysaccharide, or a salt thereof [according to claim 1, wherein] comprising:

^{13}C-cyclodextrin or at least one sugar molecule constituting the oligosaccharide or polysaccharide [is] being modified with at least one [^{13}C-labeled] modifying group,

wherein said sugar molecule or modifying group is ^{13}C-labeled, and said modifying group is selected from a group consisting of a galactosyl group, a digalactosyl group, an alkoxyl group, a carbamoyl group, a pyrimidino group, an ethylidene group, and a benzylidene group.

7. (Twice Amended) The ^{13}C-labeled oligosaccharide or polysaccharide or a salt thereof according to claim [1] 5, which is a cyclic oligosaccharide or polysaccharide.

9. (Amended) (Twice Amended) The ^{13}C-labeled oligosaccharide or polysaccharide or a salt thereof according to claim [1] 5, which is a ^{13}C-cyclodextrin or β-galactosyl-^{13}C-maltooligosaccharide.

Claims 43 to 63 have been added.

43. (New) A method of measuring pancreatic exocrine function, comprising:

administering to a subject to be tested for pancreatic exocrine function, a ^{13}C- or ^{14}C-labeled oligosaccharide or polysaccharide or a salt thereof or a derivative thereof other than ^{13}C-starch; and

measuring a ^{13}C content in an exhaled CO_2 of the subject to determine the level of pancreatic exocrine function.

44. (New) The method of measuring pancreatic exocrine function according to claim 43, wherein the ^{13}C- or ^{14}C-labeled oligosaccharide or polysaccharide or salt thereof or derivative thereof is hydrolyzed with *a*-amylase.

45. (New) The method of measuring pancreatic exocrine function according to claim 44, wherein the ^{13}C- or ^{14}C- labeled oligosaccharide or polysaccharide or salt thereof or derivative thereof is not hydrolyzed with *a*- glucosidase.

46. (New) The method of measuring pancreatic exocrine function according to claims 43, wherein the ^{13}C- or ^{14}C- labeled oligosaccharide or polysaccharide is a linear or branched oligosaccharide or polysaccharide.

47. (New) The method of measuring pancreatic exocrine function according to claim 46, wherein the ^{13}C- or ^{14}C- labeled oligosaccharide or polysaccharide is modified at the non-reducing terminal.

48. (New) The method of measuring pancreatic exocrine function according to claims 43, wherein the ^{13}C- or ^{14}C- labeled oligosaccharide or polysaccharide is a cyclic oligosaccharide or polysaccharide.

49. (New) The method of measuring pancreatic exocrine function comprising:

administering to a subject to be tested for pancreatic exocrine function, a ^{13}C- or ^{14}C-labeled inclusion complex or a salt thereof having a cyclodextrin or a modified derivative thereof as a host molecule.

50. (New) The method of measuring pancreatic exocrine function according to any one of claims 43, wherein the pancreatic exocrine function to be diagnosed is the ability of the pancreas to secrete *a*- amylase.

51. (New) The method of measuring pancreatic exocrine function according to claims 43, wherein the pancreatic exocrine function to be diagnosed is the ability of the pancreas to secrete *a* amylase and at least one pancreatic exocrine enzyme other than *a*-amylase.

52. (New) A method of measuring pancreatic exocrine function, comprising:

administering to a subject to be tested for pancreatic exocrine function, ^{13}C-cyclodextrin or at least one sugar molecule constituting the oligosaccharide or polysaccharide being modified with at least one modifying group, wherein said sugar molecule or modifying group is ^{13}C-labeled, and said modifying group is selected from a group consisting of a galactosyl group, a digalactosyl group, an alkoxyl group, a carbamoyl group, a pyrimidino group, an ethylidene group, and a benzylidene group; and

measuring a ^{13}C content in an exhaled CO_2 of the subject to determine the level of pancreatic exocrine function.

53. (New) The method according to claim 52, further comprising:

administering the oligosaccharide or polysaccharide, or salt thereof orally.

54. (New) The method according to claim 52, wherein the administered ^{13}C-labeled oligosaccharide or polysaccharide, or salt thereof is decarboxylated to generate $^{13}CO_2$ after a digestion by pancreatic secreted enzymes.

55. (New) The method according to claim 54, wherein the pancreatic secreted enzyme is *a*-amylase.

56. (New) The method according to claim 52, further comprising:

providing said oligosaccharide comprising polymerized monosaccharides of two to ten residues long.

57. (New) The method according to claim 52, further comprising:

providing said polysaccharide comprising polymerized monosaccharides of at least ten residues long.

58. (New) A method of determining whether a subject has a reduced pancreatic exocrine function, comprising:

administering to a subject to be tested for pancreatic exocrine function, ^{13}C-cyclodextrin or at least one sugar molecule constituting the oligosaccharide or polysaccharide being modified with at least one modifying group, wherein said sugar molecule or modifying group is ^{13}C-labeled, and said modifying group is selected from a group consisting of a galactosyl group, a digalactosyl group, an alkoxyl group, a carbamoyl group, a pyrimidino group, an ethylidene group, and a benzylidene group;

measuring a ^{13}C content in an exhaled CO_2 of the subject; and

comparing the ^{13}C content in the exhaled CO_2 of the subject to the level of a ^{13}C content in the exhaled CO_2 of a healthy control subject who was administered an equivalent amount of the ^{13}C-labeled oligosaccharide or polysaccharide or the pharmaceutically acceptable salt thereof,

wherein the reduced ^{13}C in the exhaled CO_2 of the subject is an indication that the subject has a reduced pancreatic exocrine function.

59. (New) The method according to claim 58, further comprising:

administering the oligosaccharide or polysaccharide, or salt thereof orally.

60. (New) The method according to claim 58, wherein the administered ^{13}C-labeled oligosaccharide or polysaccharide, or salt thereof is decarboxylated to generate $^{13}CO_2$ after a digestion by pancreatic secreted enzymes.

61. (New) The method according to claim 60, wherein the pancreatic secreted enzyme is α-amylase.

62. (New) The method according to claim 58, further comprising:

providing said oligosaccharide comprising polymerized monosaccharides of two to ten residues long.

63. (New) The method according to claim 58, further comprising:

providing said polysaccharide comprising polymerized monosaccharides of at least ten residues long.